UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION
CASE NO. 3:16-cv-344

THOMAS C. CARTER PLAINTIFFS

and

JUDITH CARTER

v.

BIOMET ORTHOPEDICS, LLC

and

BIOMET, INC.

and

BIOMET MANUFACTURING CORP.

and

BIOMET U.S. RECONSTRUCTION, LLC DEFENDANTS

COMPLAINT

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Plaintiffs, Thomas C. Carter and Judith Carter, by and through the undersigned attorneys, for their Complaint, allege as follows:

1. This is a product liability case involving a defective hip implant system. Plaintiff Thomas C. Carter ("Plaintiff") had Biomet M2a-38 Metal-on-Metal Hip Systems ("Hip System") implanted in both his hips. The Hip System suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the

femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die.

2. As a result of these defects, Plaintiff's Hip Systems have an unreasonably high risk of failing in his body, causing severe loosening of the device and/or toxic levels of cobalt and chromium, tissue and bone destruction, and the need for Plaintiff to undergo a complicated and risky surgery to remove and replace the defective implant.

PARTIES

3. Plaintiffs, Thomas C. Carter and Judith Carter, are citizens and residents of Adams Ridge Lane in Humble, Texas, which is located in Harris County and is part of the Southern District of Texas, U.S. District Court.

4. Defendant, Biomet Orthopedics, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw, Indiana. Biomet Orthopedics, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Orthopedics, LLC is a citizen of Indiana.

5. Defendant, Biomet, Inc., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet, Inc. is a citizen of Indiana.

6. Defendant, Biomet Manufacturing Corp., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Manufacturing Corp. is a citizen of Indiana.

7. Biomet U.S. Reconstruction, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw,

Indiana. Biomet U.S. Reconstruction, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant, Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet U.S. Reconstruction, LLC is a citizen of Indiana.

8. Pursuant to Case Management Order No. 2 (DN 242) filed Feb. 15, 2013, by this Court in Multi-District Litigation No. 2391, In re: Biomet M2a Magnum Hip Implant Products Liability Litigation, Defendants agree to accept service by mail.

9. At all times mentioned, each Defendant was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Hip System that is the subject of this litigation. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

10. All Defendants are collectively referred to herein as "Biomet."

JURISDICTION AND VENUE

11. This is a civil action of which U.S. District Court for the Southern District of Texas has original jurisdiction under 28 U.S.C. section 1332 because it is between citizens of different states (as described above) and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

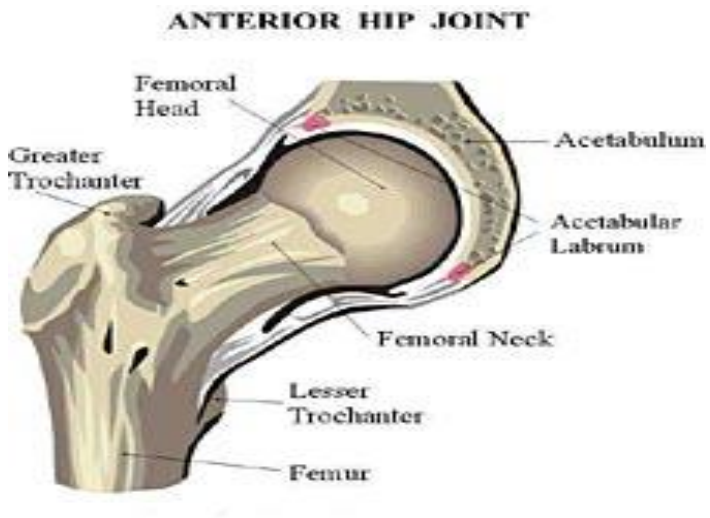
12. Venue is proper in the Southern District of Texas, U.S. District Court pursuant to 28 U.S.C. §1391 because it is the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred and all Defendants are subject to personal jurisdiction

in that District. However, pursuant to Case Management Order No. 2 (DN 242) filed Feb. 15, 2013, by this Court in Multi-District Litigation No. 2391, In re: Biomet M2a Magnum Hip Implant Products Liability Litigation, the above-captioned complaint is being filed directly in U.S. District Court in Northern Indiana.

FACTUAL BACKGROUND

A. The Hip System Is Defective and Was Not Adequately Tested

13. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



14. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal

ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

15. The Hip System used in Plaintiff's surgery, described in greater detail below, suffers from a design or manufacturing defect that causes loosening of the device and/or excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

16. The design of the Hip System was not sufficiently tested by Biomet, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

17. On numerous occasions, Biomet met with orthopedic surgeons in cities throughout the United States to promote the Hip Implant. At some or all of these meetings, a representative or representatives of Biomet was present. During these meeting, Biomet assured the orthopedic surgeons that the Hip System was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Biomet continued to "defend" the Hip Implant even after they became aware of numerous and serious complications with the M2a Magnum Hip System and various related devices. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold the Hip Implant To Plaintiff After It Knew It Was Defective, That It Had Injured Others, And That It Could Injure Her.

18. It was not long after Biomet launched the M2a Magnum Hip System that reports of failures began flooding into Biomet. For example, in August 2004, Biomet received a

complaint that a patient had to undergo a surgery to remove and replace an M2a Magnum Hip System because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

19. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum Hip System had failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associated with the M2a Magnum Hip System have been filed with the FDA. By the time Biomet sold the Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the M2a Magnum Hip System and other related systems. Consequently, Biomet was fully aware that some of its Hip Systems were defective and that dozens of patients already had been injured by that defect. Based on this information, Biomet should have recalled the metal Hip System before it was sold to Plaintiff. At minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

20. As numerous failures of Hip Implant systems were reported to Biomet, it continued to actively promote, market and defend the defective products. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum Hip System. These brochures were given to doctors around the world to encourage them to use the M2a Magnum Hip System.

21. Biomet's reason to conceal the defect in its M2a Magnum Hip System is clear. Hip implant sales are critically important to Biomet. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors. They ultimately were purchased by a private equity firm in 2007 for $10 billion. More recently, in

April 2014, managers at Biomet announced yet another sale, this time to competitor Zimmer Holdings, Inc., in a deal valued at $13.35 billion. Throughout this time period, Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the various Hip Systems despite the fact that it knew the product was defective. To this day, Biomet continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff's Hip Systems Were Defective.

22. On or about March 25, 2007, Plaintiff underwent a right hip replacement surgery by Dr. Terry Clyburn at Foundation Hospital in Houston, Texas, during which a Biomet M2a-38 metal-on-metal prosthesis, was implanted in his body. Additionally, on or about January 17, 2011, Plaintiff underwent a left hip replacement surgery, also by Dr. Terry Clyburn, also at Foundation Hospital in Houston, during which a second Biomet M2a-38 metal-on-metal prosthesis, was implanted in his body. By this time, reports of adverse events associated with the M2a Magnum, M2a 38 and other Biomet devices had been filed with the FDA and Biomet knew that the product was subject to failure due to excessive metal-on-metal wear and other factors. But Biomet refused to disclose that information to Plaintiff, his physicians, or the public.

23. Instead, Biomet misrepresented to Plaintiff and his orthopedic surgeon that the Hip System was safe and effective. In reliance on these representations, Plaintiff's orthopedic

surgeon made the decision to use the Hip System. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the Biomet Hip System.

24. As a result of the defective design, manufacture and composition of the Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant has caused him severe pain and he was forced to undergo costly and painful revision surgery on April 29, 2015 on the right side, again by Dr. Terry Clyburn at Memorial Hermann Hospital in Houston. During the surgery, Dr. Clyburn noted toxic levels of cobalt and chromium and significant amounts of metallosis. Plaintiff then was forced to undergo a second revision on Sept. 2, 2015.

25. Having to go through a first and second revision surgery has subjected Plaintiff to much greater risks of future complications than he had before the revision surgery.

26. Several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

27. As a direct and proximate result of the failure of his defective Hip Systems and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries,

pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed $75,000 jurisdictional minimum of this court.

COUNT I
(Strict Product Liability)

28. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

29. Biomet designed, manufactured, promoted, distributed, marketed, and sold the Hip System.

30. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff and his physician, without substantial change in the condition in which it was sold.

31. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the Hip System contained manufacturing defects, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(b) When placed in the stream of commerce, the Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use,

subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(c) The Hip System was insufficiently tested; and

(d) The Hip System was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff and his physicians of the full nature or extent of the risks associated with its use.

32. Biomet knew or should have known of the dangers associated with the use of the Hip System, as well as the defective nature of the Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the Hip System so as to maximize sales and profits at the expense of the public health and safety. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

33. Plaintiff and his surgeon used the Hip System as directed for its intended purpose.

34. At all times herein mentioned, the Hip System was defective, and Biomet knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Plaintiff nor his physician knew or had reason to know of the existence of the aforementioned defects. Neither Plaintiff nor his physicians could have discovered the defects in the Hip System through the exercise of reasonable care.

35. The Hip System had not been materially altered or modified prior to its implantation in Plaintiff.

36. As a direct and proximate result of the failure of the defective Hip System, Plaintiff suffered the injuries and damages as described herein.

COUNT II
(Negligence)

37. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

38. At all times herein mentioned Biomet had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

39. Biomet maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System.

40. Biomet, maliciously, recklessly and/or negligently made misrepresentations about the safety and effectiveness of the Hip System to Plaintiff and his orthopedic surgeon. In reliance on these misrepresentations, Plaintiff's orthopedic surgeon decided to use the Hip Implant in Plaintiff's surgery. If it was not for the misrepresentations by Biomet, Plaintiff's orthopedic surgeon would not have used the Hip System in Plaintiff's surgery.

41. Biomet maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Plaintiff and his physicians as to the risks of the Hip System.

42. Biomet maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Hip System when they knew or should have known of said risks.

43. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

44. As a result of Biomet's wrongful conduct, Plaintiff suffered injuries and damages as alleged herein.

COUNT III
(Breach of Implied Warranties)

45. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

46. Prior to the time that the Hip System was used by Plaintiff, Biomet impliedly warranted to Plaintiff and his physicians that the Hip System was of merchantable quality and safe and fit for the use for which it was intended.

47. Plaintiff's physicians were and are unskilled in the research, design and manufacture of the Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Biomet in using the Hip System.

48. The Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Biomet, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

49. Biomet, by selling, delivering and/or distributing the defective Hip System to Plaintiff, breached the implied warranty of merchantability and fitness and caused Plaintiff pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

50. As a result of the aforementioned breach of implied warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT IV
(Breach of Express Warranty)

51. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

52. At all times herein mentioned, Biomet expressly warranted to Plaintiff and his physicians, by and through statements made by Biomet or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned Hip System was safe, effective, fit and proper for its intended use.

53. In utilizing the aforementioned Hip System, Plaintiff and his physician relied on the skill, judgment, representations and foregoing express warranties of Biomet.

54. Said warranties and representations were false in that the aforementioned Hip System was not safe and was unfit for the uses for which it was intended.

55. As a result of the foregoing breach of express warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT V
(Violation of Texas Deceptive Trade Practices Act)

56. Plaintiff realleges and reincorporates each of the allegations above as if set forth fully herein.

57. Defendants are liable to the Plaintiff pursuant to the Texas Deceptive Trade Practices Act ("TDTPA"). As a direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff has sustained and will continue to sustain damages consisting of: past and future lost wages, medical, permanency and incidental expenses, according to proof; past and future general damages for pain and suffering, according to proof.

58. In the course of the transactions that are the subject of this lawsuit, Defendant engaged in the following unfair and deceptive acts, methods or practices:

a. Causing a probability of confusion or misunderstanding about the source, sponsorship, approval, or certification of its services;

b. Representing that its services have sponsorship, approval, characteristics, and benefits that they do not have;

c. Representing that its services were of workmanlike quality when, in fact they were not;

d. Causing a probability of confusion or of misunderstanding concerning Plaintiff's legal rights, obligations, or remedies;

e. Failing to reveal material facts, the omission of which tended to mislead or deceive Plaintiff, and which could not reasonably be known by the Plaintiff;

f. Taking or arranging for the consumer to sign an acknowledgment, certificate, or other writing affirming acceptance, delivery, compliance with a requirement of law, or other performance, when Defendant knew or had reason to know that the statement was not true;

g. Entering into a consumer transaction in which Plaintiff purportedly waived a right, benefit, or immunity provided by law, without conspicuous disclosure and without Plaintiff's specific consent;

h. Failing to provide promised benefits, including benefits arising by operation of law;

i. Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner; and

j. Such other and further acts or omissions as may be determined through further investigation and discovery.

59. Upon information and belief, the violations described above were not the result of bona fide error, in that Defendant did not have procedures in place designed to prevent injury to Plaintiff from their defective product, the defectiveness of which the Defendant had reason to know and Defendant has engaged in similar misconduct in connection with sales of other defective hip replacement implants.

60. As a result of the Defendant's actions described above, Plaintiff has suffered a loss within the meaning of the Act and is also entitled to statutory damages and attorney fees as provided in the Act.

61. Plaintiff did not become aware of the connection and/or nexus between his injuries and the above-described negligent design of the Biomet Hip System until his first revision surgery.

COUNT VI
(Loss of Consortium)

62. Plaintiff realleges and reincorporates each of the allegations above as if set forth fully herein.

63. Because of Defendants' conduct as described above, and the corresponding injuries sustained by Plaintiff's spouse, Plaintiff Judith Carter is entitled to recover for the loss of services, assistance, aid, society, companionship, and conjugal relationship between her and her

husband Thomas C. Carter.

PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

1. Past and future lost wages, medical, permanency and incidental expenses, according to proof;
2. Past and future general damages for pain and suffering, according to proof;
3. Punitive and exemplary damages in an amount to be determined at trial;
4. Prejudgment and post judgment interest;
5. Costs to bring this action; and
6. Such other and further relief as the court may deem just and proper.

Respectfully submitted,

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